

Procedures for External Peer Review of Intramural Projects

(Updated May 26, 2005)

Introduction

The following describes the procedures for using external peer review to help evaluate and improve intramural research projects. The procedures apply to the review of new projects within the first year of initiation. It should help employees to understand the process by which their research will be evaluated by external peers to help validate and improve that research. Topics discussed include the background of new legal requirements for peer review of internal Federal research, relevant policies of CDC and NIOSH, and the procedures initiated in the Mining Program to implement these policies. The procedures are designed to help ensure the quality of the internal research done at the Mining Program laboratories, to satisfy the legal and policy requirements, and to minimize additional administrative burden on researchers and the external reviewers who assist NIOSH with this effort.

Background

The Mining Program has been using external peer reviewers to help evaluate and improve project proposals for new intramural research projects since 2000. External reviewers have also evaluated Mining Program protocols under some major research projects.

In January, 2002, the Office of Management and Budget issued its "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" in response to the Federal Data Quality Act (Public Law 106-554 Section 1(a)(3)[515]) passed by Congress in 2000. These guidelines require all agencies to adopt a basic standard of quality as a performance goal and to incorporate information quality criteria into agency information dissemination practices beginning October 1, 2002. Subsequently, HHS developed a draft of its own data quality guidelines to implement the OMB requirements within the Department. CDC and NIOSH have also developed policy statements on external peer review of intramural research. NIOSH issued an updated policy on external peer review of intramural research projects in May 2005. Most of the responsibilities under the NIOSH policy statement are delegated to the NIOSH Divisions and Laboratories. It is the responsibility of the Divisions to ensure that Division projects receive the appropriate level of review, that the review is conducted and documented according to the guidelines, and that the reviewers' comments are addressed in a reasonable fashion.

Each NIOSH Division and Laboratory is responsible for,

1. Developing a plan for conducting peer review of Division projects;
2. Identifying on an ongoing basis new projects and continuing projects that require review, and the level and type of review required for each;
3. Conducting the peer review.
 - a. Providing the project staff with guidelines in preparing the project proposal or protocol;
 - b. Selecting reviewers for the project who are free from conflicts of interest;
 - c. Conducting the review by mail, e-mail, or face-to-face meeting;
 - d. Providing review comments and critiques to project staff;
 - e. Ensure that the review proceedings are in compliance with the Federal Advisory Committee Act (FACA).
4. Determining what follow-up is appropriate to address reviewer comments. Follow-up steps could include any or all of the following:
 - a. Follow-up conversations with the reviewer and the project officer to clarify reviewer recommendations and concerns;

- b. Written response from the project officer on major reviewer comments. (Written responses do not need to be sent to the reviewer, but should be included in the review documentation file);
 - c. Recruitment of additional reviewers, if necessary;
 - d. Modification to the project proposal to address reviewer concerns (with or without a second round of review).
- 5. Keeping a list of projects receiving review each fiscal year. For projects that are exempted from review (i.e. the project is not reviewed even though it is a new project or an ongoing projects that has not been reviewed in five years), the documentation should state why the project was exempt;
- 6. Documenting and certifying the review process. Necessary documentation includes:
 - a. Qualifications of reviewers;
 - b. Any possible conflicts of interest of reviewers, including signed conflict of interest forms for each reviewer;
 - c. A copy of the project proposal or protocol;
 - d. A brief synopsis of how the review was conducted;
 - e. Comments and critiques from the reviewers;
 - f. A description of any follow-up steps taken to address review comments, including written response from the project officer on major reviewer comments, and a description of any resulting changes to the project proposal or protocol;

New Projects

All new Mining Program research projects must be peer reviewed by external experts within the first year of the project. Research projects are those projects, which have their own CAN (account number) in IRIS and which are considered primarily research. The only current projects with CAN's in the Mining Program which would be excluded from this policy are the Office of the Director (OD) and Branch CAN's which cover planning and management of research, but do not include research tasks themselves. The Lake Lynn CAN is also excluded, because it covers operation of a facility, and the research done at that facility is included in, and is reviewed under the research projects done at the facility. New pilot projects with planned duration of one year or less may also be excluded at the discretion of the Laboratory Director.

Prior to the beginning of each fiscal year, the Mining Program management solicits and evaluates concepts or mini-proposals for new research projects. Management may decide through their review and evaluation to have some of these concepts developed into detailed project proposals in a format similar to that used for applications for NIOSH research grants (see Related Documents.). The project proposals will be sent out for external peer review prior to the beginning of the new fiscal year. Some new projects may be initiated before external peer review is done. Reasons for this could include need for quick response to a newly identified high priority problem, or that the project requires preparation of a detailed research protocol in the first year. Such projects would prepare either research plans in the grant format, or detailed research protocols, which would be sent for external peer review within the first year after project initiation. A checklist and guide for research protocols can be found in the Related Documents.

Reviewers

The *appearance* of conflict of interest is often as important as any actual bias in the review process. It is important that peer reviewers be chosen to avoid both real and perceived conflicts of interest, whether the conflicts are financial, personal, or professional in nature.

Reviewers are to be avoided for external peer review if they fall into one of the following categories:

1. NIOSH or CDC employees;
2. Current recipients of funding (i.e. contracts or cooperative agreements) involving the project staff;
3. Those who are likely to collaborate or apply for funding under the proposed work;
4. Current collaborators, close personal friends, or family members of the project staff;

In addition to the categories listed above, there are broader types of conflict of interest that should be avoided if possible:

5. HHS employees;
6. Recipients of NIOSH contracts or cooperative agreements (even if from elsewhere in NIOSH);
7. Reviewers with personal or professional conflicts of interest with the project staff, including recent collaborators, students, or teachers, or those who have had long-standing professional or personal differences;
8. Reviewers who might otherwise give the appearance of a conflict of interest or lack of objectivity. For example, reviewers who have strongly held professional or policy related position related to the proposed work should be avoided if their position is likely to affect their objectivity as a reviewer.

It may not be possible to meet criteria 5-8 above in every case. Ideally, the perfect reviewer would be someone from outside the government who is a leading expert in the field, has had no ties to NIOSH or the researcher, and is completely objective about the area of research in the proposal. Obviously, the perfect reviewer may not exist, especially in narrow fields of research, and inevitably there will be trade-offs made when judging the relative importance of conflicts of interest versus the other qualifications of the reviewer.

Most Mining Program research projects will require reviewers with at least some knowledge of mines, mining methods and equipment, and the mining environment. Reviewers must also be technical experts in their fields with knowledge of scientific research methodology. The number of persons in the U.S. who are very knowledgeable about both mining and scientific research is limited. As a result it is probable that many of the best external peer reviewers will be persons who have had prior interactions with NIOSH researchers and who have worked with NIOSH staff or have received NIOSH funding.

All reviewers are asked to disclose anything that might be perceived as a possible conflict of interest. As an additional aid in avoiding conflicts of interest, the Mining Program normally keeps the reviews blind, i.e. avoids revealing the identity of the reviewers to the staff whose project is being reviewed. The Mining Program does not normally pay persons doing written reviews of these documents, unless the review requires any on-site visits to the Mining Program Laboratories.

Review Criteria

Prior to being sent for external review, draft project proposals are reviewed internally by the author's section and branch chiefs, and the appropriate Laboratory Director, Deputy Director, and Associate Director for Science (if applicable). The proposal or protocol must provide sufficient detail to enable reviewers to determine the suitability of the study design and methods for accomplishing the proposed work. Proposals are returned if they need correction or do not meet minimum standards. Acceptable proposals are also sent to the Associate Director for Mining and Construction for approval prior to external review.

Proposals which pass internal review are sent to two or more external peer reviewers.

These reviewers are asked assess the overall impact that the project could have on the field taking into account, among other factors:

1. The significance of the goals of the proposed research, from a scientific or technical standpoint, and expected impact on injury reduction or health hazard exposure;
2. The adequacy of the approach and methodology proposed to carry out the research;
3. The innovativeness and originality of the proposed research;
4. The qualifications and experience of the principal investigator and proposed staff;
5. The scientific environment and reasonable availability of resources necessary to the research; and
6. The reasonableness of the proposed budget and duration in relation to the proposed research.

Reviewers are told that the primary usefulness of their review will be to provide constructive help in improving the research. To do so, they should provide comments on the strengths and weaknesses of the project plans and suggestions for how they might be improved. They are not asked to give any evaluation score or to make comparisons between the plan they are reviewing and any other research plans. The reviewers are asked to complete their reviews and provide the results within four to six weeks. Normally reviews of new projects are done by E-mail or regular mail. A sample letter to reviewers is attached as an appendix.

Response to Reviews

The reviews are requested by and returned to the appropriate Mining Program Division. The review comments are forwarded to project PI and their supervisors, after any identifiers of the reviewer have been removed. The project PI will provide to the OD, a written response to the review comments and revised research plans with any changes, which are made as a result of the review. The Mining Program Division maintains a file containing the written reviews, comments in response to the reviews, and the research plans and protocols. If the reviewer has asked for feedback on the results of the review, the Mining Program Division will provide a response to the reviewer. In any case, reviewers are sent a thank you note for their help by letter or E-mail.

Projects Exceeding Five Years Duration

Very few projects in the Mining Program would be expected to continue for more than five years. Any project, which has continued for four years, will be examined to determine if it should be completed in the fifth year or continued. If the work is to be continued, the project will be treated as a new project whether under the same or new title and CAN. New research plans will be prepared for such projects and evaluated by external peer review in the same manner as any other new research project.

Appendices

1. Sample letter to external peer reviewers
2. Research planning and evaluation flow chart

Related Documents

1. Mining Program research project proposal instructions
2. Project proposal form
3. Project budget form
4. Protocol checklist and guide (separate file); also at <http://inside.niosh.cdc.gov/hsrb/pdfs/protocolchecklist.pdf>
5. Hints for writing project proposals

Appendix

Sample Letter to Reviewer

Dear Dr. Smith:

Thank you for agreeing to review a proposal for a new research project at the NIOSH Pittsburgh Research Laboratory. NIOSH has adopted the practice of having all internal project proposals peer reviewed. The goal is to ensure that we use our limited intramural budget to fund high quality work that will improve mine safety and health. Of course, the success of this process depends upon the willingness of experts such as you to carefully review the proposals. We know that it is not easy to find time to take on these additional activities, and accordingly, we are delighted that you have agreed to participate as a technical reviewer.

The proposal for which we have requested your review is attached. The project title is, "Guidelines for Eliminating Hazardous Ground Conditions from Underground Stone Mines". The proposals for new internal mining projects have been developed in a format similar to that requested for applications to NIOSH's extramural research grant program. We are asking you to assist us in the evaluation of the proposals, using the criteria outlined below. The results of your evaluation will be released to the principal investigator, but your identity will not be disclosed unless you request it.

Please review and assess the overall impact that the project could have on the field taking into account, among other factors:

1. The significance of the goals of the proposed research, from a scientific or technical standpoint, and expected impact on injury reduction or health hazard exposure;
2. The adequacy of the approach and methodology proposed to carry out the research;
3. The innovativeness and originality of the proposed research;
4. The qualifications and experience of the principal investigator and proposed staff;
5. The scientific environment and reasonable availability of resources necessary to the research;
6. The reasonableness of the proposed budget and duration in relation to the proposed research.

The primary usefulness of the review will be to provide constructive help in improving the research. To do so, please provide comments on the strengths and weaknesses of the project plans and suggestions for how they might be improved. You do not need to give any evaluation score, or to make comparisons between this proposal and any others.

Please provide your completed review by May 31. If this is going to present a problem, notify me as soon as possible. Please return your review comments by either regular mail or E-mail to me:

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We are not aware of any conflict of interest that might interfere with your review of the proposal. However, if you think that there might be any appearance of a possible conflict of interest, please contact me to discuss the situation. It would be helpful if you could provide a brief CV or resume along with your review, which will help us to document the credentials of our external reviewers for our files.

Thank you again for your assistance in this review process. Contact me if you have any questions.

Sincerely yours,

John A. Breslin
Associate Director for Science
NIOSH Pittsburgh Research Laboratory

Research Planning and Evaluation Process

